

106TH CONGRESS
1ST SESSION

H. R. 1798

To amend the Public Health Service Act to provide additional support for and to expand clinical research programs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 13, 1999

Mr. GREENWOOD (for himself, Mrs. LOWEY, Mrs. JOHNSON of Connecticut, Mr. BROWN of Ohio, Mr. BURR of North Carolina, Mr. WAXMAN, Mr. PICKERING, Mr. DEAL of Georgia, Mrs. MORELLA, Mr. FRANK of Massachusetts, Ms. DELAURO, Mr. NETHERCUTT, Mr. LEACH, Mr. ENGLISH, Mr. TOWNS, Mr. COYNE, Mr. LEWIS of Georgia, Mr. NADLER, Mr. WICKER, Mr. FILNER, and Ms. PELOSI) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Public Health Service Act to provide additional support for and to expand clinical research programs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the "Clinical Research En-
5 hancement Act of 1999".

1 SEC. 2. FINDINGS AND PURPOSE.

2 (a) FINDINGS.—Congress makes the following find-
3 ings:

4 (1) Clinical research is critical to the advance-
5 ment of scientific knowledge and to the development
6 of cures and improved treatment for disease.

7 (2) Tremendous advances in biology are open-
8 ing doors to new insights into human physiology,
9 pathophysiology and disease, creating extraordinary
10 opportunities for clinical research.

11 (3) Clinical research includes translational re-
12 search which is an integral part of the research
13 process leading to general human applications. It is
14 the bridge between the laboratory and new methods
15 of diagnosis, treatment, and prevention and is thus
16 essential to progress against cancer and other dis-
17 eases.

18 (4) The United States will spend more than \$1
19 trillion on health care in 1997, but the Federal
20 budget for health research at the National Institutes
21 of Health was \$12.7 billion, only 1 percent of that
22 total.

23 (5) Studies at the Institute of Medicine, the
24 National Research Council, and the National Acad-
25 emy of Sciences have all addressed the current prob-
26 lems in clinical research.

(6) The Director of the National Institutes of Health has recognized the current problems in clinical research and appointed a special advisory committee, which recommended expanded support for existing NIH clinical research programs and the creation of new initiatives to recruit and retain clinical investigators.

(7) The current level of training and support for health professionals in clinical research is fragmented, frequently undervalued, and potentially underfunded.

(8) Young investigators are not only apprentices for future positions but a crucial source of energy, enthusiasm, and ideas in the day-to-day research that constitutes the scientific enterprise. Serious questions about the future of life-science research are raised by the following:

(A) The number of young investigators applying for grants dropped by 54 percent between 1985 and 1993.

(B) The number of physicians applying for first-time NIH research project grants fell from 838 in 1994 to 575 in 1997, a 31% reduction.

(C) Newly independent life-scientists are expected to raise funds to support their new re-

1 search programs and a substantial proportion
2 of their own salaries.

3 (9) The following have been cited as reasons for
4 the decline in the number of active clinical research-
5 ers, and those choosing this career path:

6 (A) A medical school graduate incurs an
7 average debt of \$85,619, as reported in the
8 Medical School Graduation Questionnaire by
9 the American Association of Medical Colleges
10 (AAMC).

11 (B) The prolonged period of clinical train-
12 ing required increases the accumulated debt
13 burden.

14 (C) The decreasing number of mentors and
15 role models.

16 (D) The perceived instability of funding
17 from the National Institutes of Health and
18 other Federal agencies.

19 (E) The almost complete absence of clin-
20 ical research training in the curriculum of
21 training grant awardees.

22 (F) Academic Medical Centers are experi-
23 encing difficulties in maintaining a proper envi-
24 ronment for research in a highly competitive
25 health care marketplace, which are compounded

1 by the decreased willingness of third party pay-
2 ers to cover health care costs for patients en-
3 gaged in research studies and research proce-
4 dures.

5 (10) In 1960, general clinical research centers
6 were established under the Office of the Director of
7 the National Institutes of Health with an initial ap-
8 propriation of \$3,000,000.

9 (11) Appropriations for general clinical research
10 centers in fiscal year 1998 equaled \$167,000,000.
11 Since the late 1960s, spending for general clinical
12 research centers has declined from approximately
13 3% to 1% of the NIH budget.

14 (12) In fiscal year 1998, there were 75 general
15 clinical research centers in operation, supplying pa-
16 tients in the areas in which such centers operate
17 with access to the most modern clinical research and
18 clinical research facilities and technologies.

19 (b) PURPOSE.—It is the purpose of this Act to pro-
20 vide additional support for and to expand clinical research
21 programs.

1 SEC. 3. INCREASING THE INVOLVEMENT OF THE NATIONAL
2 INSTITUTES OF HEALTH IN CLINICAL
3 RESEARCH.

4 Section 402 of the Public Health Service Act (42
5 U.S.C. 282) is amended by adding at the end the fol-
6 lowing:

7 “(m)(1) The Director of NIH shall undertake activi-
8 ties to support and expand the involvement of the National
9 Institutes of Health in clinical research.

10 “(2) In carrying out paragraph (1), the Director of
11 NIH shall—

12 “(A) implement the recommendations of the Di-
13 vision of Research Grants Clinical Research Study
14 Group and other recommendations for enhancing
15 clinical research, where applicable; and

16 “(B) establish an intramural clinical research
17 fellowship program and a continuing education clin-
18 ical research training program at NIH.

19 “(3) The Director of NIH, in cooperation with the
20 Directors of the Institutes, Centers, and Divisions of the
21 National Institutes of Health, shall support and expand
22 the resources available for the diverse needs of the clinical
23 research community, including inpatient, outpatient, and
24 critical care clinical research.

25 “(4) The Director of NIH shall establish peer review
26 mechanisms to evaluate applications for—

1 “(A) Mentored Patient-Oriented Research Ca-
2 reer Development Awards;

3 “(B) Mid-Career Investigator Awards in Pa-
4 tient-Oriented Research;

5 “(C) graduate training in clinical investigation
6 awards;

7 “(D) intramural clinical research fellowships.

8 Such review mechanisms shall include individuals who are
9 exceptionally qualified to appraise the merits of potential
10 clinical research training and research grant proposals.”.

11 **SEC. 4. GENERAL CLINICAL RESEARCH CENTERS.**

12 Part B of title IV of the Public Health Service Act
13 (42 U.S.C. 284 et seq.) is further amended by adding at
14 the end the following:

15 **“SEC. 409C. GENERAL CLINICAL RESEARCH CENTERS.**

16 “(a) GRANTS.—The Director of the National Center
17 for Research Resources shall award grants for the estab-
18 lishment of general clinical research centers to provide the
19 infrastructure for clinical research including clinical re-
20 search training and career enhancement. Such centers
21 shall support clinical studies and career development in
22 all settings of the hospital or academic medical center in-
23 volved.

24 “(b) ACTIVITIES.—In carrying out subsection (a), the
25 Director of NIH shall expand the activities of the general

1 clinical research centers through the increased use of tele-
2 communications and telemedicine initiatives.

3 “(c) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated such sums as may be necessary for
6 each fiscal year.

7 “SEC. 409D. ENHANCEMENT AWARDS.

8 “(a) MENTORED PATIENT-ORIENTED RESEARCH CA-
9 REER DEVELOPMENT AWARDS.—

10 “(1) IN GENERAL.—The Director of the Na-
11 tional Center for Research Resources shall make
12 grants (to be referred to as ‘Mentored Patient-Ori-
13 ented Research Career Development Awards’) to
14 support individual careers in clinical research at gen-
15 eral clinical research centers or at other institutions
16 that have the infrastructure and resources deemed
17 appropriate for conducting patient-oriented clinical
18 research. The Director of the National Center for
19 Research Resources shall, where practicable, collabo-
20 rate or consult with other Institute Directors in
21 making awards under this subsection.

22 “(2) APPLICATIONS.—An application for a
23 grant under this subsection shall be submitted by an
24 individual scientist at such time as the Director may
25 require.

1 “(3) AUTHORIZATION OF APPROPRIATIONS.—

2 For the purpose of carrying out this subsection,
3 there are authorized to be appropriated such sums
4 as may be necessary for each fiscal year.

5 “(b) MID-CAREER INVESTIGATOR AWARDS IN PA-
6 TIENT-ORIENTED RESEARCH.—

7 “(1) IN GENERAL.—The Director of the Na-
8 tional Center for Research Resources shall make
9 grants (to be referred to as ‘Mid-Career Investigator
10 Awards in Patient-Oriented Research’) to support
11 individual clinical research projects at general clin-
12 ical research centers or at other institutions that
13 have the infrastructure and resources deemed appro-
14 priate for conducting patient-oriented clinical re-
15 search. The Director of the National Center for Re-
16 search Resources shall, where practicable, collabo-
17 rate or consult with other Institute Directors in
18 making awards under this subsection.

19 “(2) APPLICATIONS.—An application for a
20 grant under this subsection shall be submitted by an
21 individual scientist at such time as the Director re-
22 quires.

23 “(3) AUTHORIZATION OF APPROPRIATIONS.—

24 For the purpose of carrying out this subsection,

1 there are authorized to be appropriated such sums
2 as may be necessary for each fiscal year.

3 “(c) GRADUATE TRAINING IN CLINICAL INVESTIGA-
4 TION AWARD.—

5 “(1) IN GENERAL.—The Director of the Na-
6 tional Center for Research Resources shall make
7 grants (to be referred to as ‘graduate training in
8 clinical investigation awards’) to support individuals
9 pursuing master’s or doctoral degrees in clinical in-
10 vestigation.

11 “(2) APPLICATIONS.—An application for a
12 grant under this subsection shall be submitted by an
13 individual scientist at such time as the Director may
14 require.

15 “(3) LIMITATIONS.—Grants shall be for terms
16 of 2 years or more and will provide stipend, tuition,
17 and institutional support for individual advanced de-
18 gree programs in clinical investigation.

19 “(4) DEFINITION.—As used in this subsection,
20 the term ‘advanced degree programs in clinical in-
21 vestigation’ means programs that award a master’s
22 or Ph.D. degree after 2 or more years of training in
23 areas such as the following:

24 “(A) Analytical methods, biostatistics, and
25 study design.

1 “(B) Principles of clinical pharmacology
2 and pharmacokinetics.

3 “(C) Clinical epidemiology.

4 “(D) Computer data management and
5 medical informatics.

6 “(E) Ethical and regulatory issues.

7 “(F) Biomedical writing.

8 “(5) AUTHORIZATION OF APPROPRIATIONS.—

9 For the purpose of carrying out this subsection,
10 there are authorized to be appropriated such sums
11 as may be necessary for each fiscal year.”.

12 **SEC. 5. CLINICAL RESEARCH ASSISTANCE.**

13 (a) NATIONAL RESEARCH SERVICE AWARDS.—Sec-
14 tion 487(a)(1)(C) of the Public Health Service Act (42
15 U.S.C. 288(a)(1)(C)) is amended by striking “50 such”
16 and inserting “100 such”.

17 (b) LOAN REPAYMENT PROGRAM.—Section 487E of
18 the Public Health Service Act (42 U.S.C. 288–5) is
19 amended—

20 (1) in the section heading, by striking “FROM
21 DISADVANTAGED BACKGROUNDS”;

22 (2) in subsection (a)(1)—

23 (A) by striking “who are from disadvan-
24 taged backgrounds”; and

1 (B) by striking “as employees of the Na-
2 tional Institutes of Health” and inserting “as
3 part of a clinical research training position”;

4 (3) in subsection (a), by striking paragraph (3)
5 and inserting the following:

6 “(3) APPLICABILITY OF CERTAIN PROVISIONS
7 REGARDING OBLIGATED SERVICE.—With respect to
8 the National Health Service Corps Loan Repayment
9 Program established under subpart III of part D of
10 title III, the provisions of such subpart shall, except
11 as inconsistent with this section, apply to the pro-
12 gram established in this section in the same manner
13 and to the same extent as such provisions apply to
14 such loan repayment program.”;

15 (4) in subsection (b)—

16 (A) by striking “Amounts” and inserting
17 the following:

18 “(1) IN GENERAL.—Amounts”; and

19 (B) by adding at the end the following:

20 “(2) DISADVANTAGED BACKGROUNDS SET-
21 ASIDE.—In carrying out this section, the Secretary
22 shall ensure that not less than 50 percent of the
23 contracts involve those appropriately qualified health
24 professionals who are from disadvantaged back-
25 grounds.”; and

1 (5) by adding at the end the following:

2 “(c) DEFINITION.—As used in subsection (a)(1), the
3 term ‘clinical research training position’ means an indi-
4 vidual serving in a general clinical research center or in
5 clinical research at the National Institutes of Health, or
6 a physician receiving a clinical research career enhance-
7 ment award, or a graduate training in clinical investiga-
8 tion award.

9 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
10 purpose of carrying out this section, there are authorized
11 to be appropriated such sums as may be necessary for
12 each fiscal year.”.

13 **SEC. 6. DEFINITION.**

14 Section 409 of the Public Health Service Act (42
15 U.S.C. 284d) is amended—

16 (1) by striking “For purposes” and inserting
17 “(a) HEALTH SERVICE RESEARCH.—For purposes”;
18 and

19 (2) by adding at the end the following:

20 “(b) CLINICAL RESEARCH.—As used in this title, the
21 term ‘clinical research’ means patient oriented clinical re-
22 search conducted with human subjects, or research on the
23 causes and consequences of disease in human populations
24 involving material of human origin (such as tissue speci-
25 mens and cognitive phenomena) for which an investigator



1 or colleague directly interacts with human subjects in an
2 outpatient or inpatient setting to clarify a problem in
3 human physiology, pathophysiology, or disease; or epi-
4 demiologic or behavioral studies, outcomes research, or
5 health services research, or developing new technologies or
6 therapeutic interventions.”.

7 **SEC. 7. OVERSIGHT BY GENERAL ACCOUNTING OFFICE.**

8 Not later than 18 months after the date of the enact-
9 ment of this Act, the Comptroller General of the United
10 States shall submit to the Congress a reporting describing
11 the extent to which the National Institutes of Health has
12 complied with the amendments made by this Act.

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